

Docket No.: UPAP0002-100  
PATENT

Serial Number: 09/359,975  
Filed: July 23, 1999

**In the Claims:**

Please amend claims 58, 59, 63, 64, and 122-125 as follows:

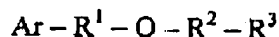
**1-57. (canceled)**

**58. (Currently Amended)** A pharmaceutical composition comprising:

a) a polynucleotide function enhancer; and

b) A DNA molecule that comprises a DNA sequence that encodes an antigen from an intracellular pathogen; wherein

i) said polynucleotide function enhancer is a compound having one of the following formulas:



or



or



or



wherein:

Ar is benzene, *p*-aminobenzene, *m*-aminobenzene, *o*-aminobenzene, substituted benzene, substituted *p*-aminobenzene, substituted *m*-aminobenzene, substituted *o*-aminobenzene, wherein the amino group in the aminobenzene compounds can be amino, C<sub>1</sub>-C<sub>3</sub> alkylamine, C<sub>1</sub>-C<sub>5</sub>, C<sub>1</sub>-C<sub>5</sub> dialkylamine and substitutions in substituted compounds are halogen, C<sub>1</sub>-C<sub>3</sub> alkyl and C<sub>1</sub>-C<sub>5</sub> alkoxy;

R<sup>1</sup> is C=O;

R<sup>2</sup> is C<sub>1</sub>-C<sub>10</sub> alkyl including branched alkyls;

R<sup>3</sup> is hydrogen, amine, C<sub>1</sub>-C<sub>5</sub> alkylamine, C<sub>1</sub>-C<sub>5</sub>, C<sub>1</sub>-C<sub>5</sub> dialkylamine;

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$R^2 + R^3$  can form a cyclic alkyl, a  $C_1$ - $C_{10}$  alkyl substituted cyclic alkyl, a cyclic aliphatic amine, a  $C_1$ - $C_{10}$  alkyl substituted cyclic aliphatic amine, a heterocycle, a  $C_1$ - $C_{10}$  alkyl substituted heterocycle including a  $C_1$ - $C_{10}$  alkyl N-substituted heterocycle;

$R^4$  is Ar,  $R^2$  or  $C_1$ - $C_5$  alkoxy, a cyclic alkyl, a  $C_1$ - $C_{10}$  alkyl substituted cyclic alkyl, a cyclic aliphatic amine, a  $C_1$ - $C_{10}$  alkyl substituted cyclic aliphatic amine, a heterocycle, a  $C_1$ - $C_{10}$  alkyl substituted heterocycle and a  $C_1$ - $C_{10}$  alkoxy substituted heterocycle including a  $C_1$ - $C_{10}$  alkyl N-substituted heterocycle;

$R^5$  is  $C=NH$ ;

$R^6$  is Ar,  $R^2$  or  $C_1$ - $C_5$  alkoxy, a cyclic alkyl, a  $C_1$ - $C_{10}$  alkyl substituted cyclic alkyl, a cyclic aliphatic amine, a  $C_1$ - $C_{10}$  alkyl substituted cyclic aliphatic amine, a heterocycle, a  $C_1$ - $C_{10}$  alkyl substituted heterocycle and a  $C_1$ - $C_{10}$  alkoxy substituted heterocycle including a  $C_1$ - $C_{10}$  alkyl N-substituted heterocycle; and,

$R^7$  is Ar,  $R^2$  or  $C_1$ - $C_5$  alkoxy, a cyclic alkyl, a  $C_1$ - $C_{10}$  alkyl substituted cyclic alkyl, a cyclic aliphatic amine, a  $C_1$ - $C_{10}$  alkyl substituted cyclic aliphatic amine, a heterocycle, a  $C_1$ - $C_{10}$  alkyl substituted heterocycle and a  $C_1$ - $C_{10}$  alkoxy substituted heterocycle including a  $C_1$ - $C_{10}$  alkyl N-substituted heterocycle; and,

ii) said DNA sequence operatively linked to regulatory sequences which control the expression of said DNA sequence.

59. (Currently Amended)

The pharmaceutical composition of claim 58 wherein said DNA molecule is a plasmid.

60-62. (canceled)

63. (Currently Amended)

The pharmaceutical composition of claim 58 wherein said antigen is a viral antigen.

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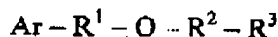
64. (Currently Amended) The pharmaceutical composition of claim 63 wherein said pathogen is a virus selected from the group consisting of: human immunodeficiency virus, HIV; Human T cell leukemia virus, HTLV; influenza virus; hepatitis A virus; hepatitis B virus; hepatitis C virus; human papilloma virus, HPV; Herpes simplex 1 virus, HSV1; Herpes simplex 2 virus, HSV2; Cytomegalovirus, CMV; Epstein-Barr virus, EBR; rhinovirus; and, coronavirus.

65-114. (canceled)

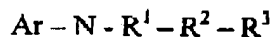
115. (previously presented) A method of introducing DNA molecules into cells of an individual comprising the steps of:

injecting into tissue of said individual at a site on said individual's body, DNA molecules and a polynucleotide function enhancer; wherein

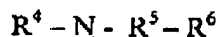
i) said polynucleotide function enhancer is a compound having one of the following formulas:



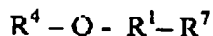
or



or



or



wherein:

Ar is benzene, *p*-aminobenzene, *m*-aminobenzene, *o*-aminobenzene, substituted benzene, substituted *p*-aminobenzene, substituted *m*-aminobenzene, substituted *o*-aminobenzene, wherein the amino group in the aminobenzene compounds can be amino, C<sub>1</sub>-C<sub>5</sub> alkylamine, C<sub>1</sub>-C<sub>5</sub>, C<sub>1</sub>-C<sub>5</sub> dialkylamine and substitutions in substituted compounds are halogen, C<sub>1</sub>-C<sub>5</sub> alkyl and C<sub>1</sub>-C<sub>5</sub>

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alkoxy;

$R^1$  is  $C=O$ ;

$R^2$  is  $C_1$ - $C_{10}$  alkyl including branched alkyls;

$R^3$  is hydrogen, amine,  $C_1$ - $C_5$  alkylamine,  $C_1$ - $C_5$ ,  $C_1$ - $C_5$  dialkylamine;

$R^2 + R^3$  can form a cyclic alkyl, a  $C_1$ - $C_{10}$  alkyl substituted cyclic alkyl, a cyclic aliphatic amine, a  $C_1$ - $C_{10}$  alkyl substituted cyclic aliphatic amine, a heterocycle, a  $C_1$ - $C_{10}$  alkyl substituted heterocycle including a  $C_1$ - $C_{10}$  alkyl N-substituted heterocycle;

$R^4$  is Ar,  $R^2$  or  $C_1$ - $C_5$  alkoxy, a cyclic alkyl, a  $C_1$ - $C_{10}$  alkyl substituted cyclic alkyl, a cyclic aliphatic amine, a  $C_1$ - $C_{10}$  alkyl substituted cyclic aliphatic amine, a heterocycle, a  $C_1$ - $C_{10}$  alkyl substituted heterocycle and a  $C_1$ - $C_{10}$  alkoxy substituted heterocycle including a  $C_1$ - $C_{10}$  alkyl N-substituted heterocycle;

$R^5$  is  $C=NH$ ;

$R^6$  is Ar,  $R^2$  or  $C_1$ - $C_5$  alkoxy, a cyclic alkyl, a  $C_1$ - $C_{10}$  alkyl substituted cyclic alkyl, a cyclic aliphatic amine, a  $C_1$ - $C_{10}$  alkyl substituted cyclic aliphatic amine, a heterocycle, a  $C_1$ - $C_{10}$  alkyl substituted heterocycle and a  $C_1$ - $C_{10}$  alkoxy substituted heterocycle including a  $C_1$ - $C_{10}$  alkyl N-substituted heterocycle; and,

$R^7$  is Ar,  $R^2$  or  $C_1$ - $C_5$  alkoxy, a cyclic alkyl, a  $C_1$ - $C_{10}$  alkyl substituted cyclic alkyl, a cyclic aliphatic amine, a  $C_1$ - $C_{10}$  alkyl substituted cyclic aliphatic amine, a heterocycle, a  $C_1$ - $C_{10}$  alkyl substituted heterocycle and a  $C_1$ - $C_{10}$  alkoxy substituted heterocycle including a  $C_1$ - $C_{10}$  alkyl N-substituted heterocycle; and,

ii) said DNA molecules are taken up by cells in said tissue.

116. (previously presented) The method of claim 115 wherein said DNA molecule comprises a DNA sequence that encodes a protein, said DNA sequence operatively linked to regulatory sequences which control the expression of said DNA sequence.

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**117. (previously presented)** The method of claim 115 wherein said DNA molecule is a plasmid.

**118. (previously presented)** The method of claim 115 wherein said tissue includes skin and muscle.

**119. (previously presented)** The method of claim 115 wherein said tissue is skin.

**120. (previously presented)** The method of claim 115 wherein said tissue is muscle.

**121. (previously presented)** The method of claim 120 wherein said tissue is skeletal muscle.

**122. (Currently Amended)** A pharmaceutical composition according to claim 58, wherein said polynucleotide function enhancer is a compound having the formula  $Ar-R^1-O-R^2-R^3$ .

**123. (Currently Amended)** The pharmaceutical composition of claim 122 wherein said DNA molecule is a plasmid.

**124. (Currently Amended)** The pharmaceutical composition of claim 122 wherein said antigen is a viral antigen.

**125. (previously presented)** The pharmaceutical composition of claim 124 wherein said pathogen is a virus selected from the group consisting of: human immunodeficiency virus, HIV; Human T cell leukemia virus, HTLV; influenza virus; hepatitis A virus; hepatitis B virus; hepatitis C virus; human papilloma virus, HPV; Herpes simplex 1 virus, HSV1; Herpes simplex 2 virus, HSV2; Cytomegalovirus, CMV; Epstein-Barr virus, EBR; rhinovirus; and, coronavirus.

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**126-140 (canceled)**

**141. (previously presented)** A method of introducing DNA molecules into cells of an individual according to claim 115, wherein said polynucleotide function enhancer is a compound having the formula  $\text{Ar}-\text{R}^1-\text{O}-\text{R}^2-\text{R}^3$ .

**142. (previously presented)** The method of claim 141 wherein said DNA molecule comprises a DNA sequence that encodes a protein, said DNA sequence being operatively linked to regulatory sequences which control the expression of said DNA sequence.

**143. (previously presented)** The method of claim 141 wherein said DNA molecule is a plasmid.

**144. (previously presented)** The method of claim 141 wherein said tissue includes skin and muscle.

**145. (previously presented)** The method of claim 141 wherein said tissue is skin.

**146. (previously presented)** The method of claim 141 wherein said tissue is muscle.

**147. (previously presented)** The method of claim 146 wherein said tissue is skeletal muscle.

**148. (previously presented)** A method of inducing antibodies against an antigen in an individual comprising the steps of:

injecting into tissue of said individual at a site on said individual's body, a DNA molecule and a polynucleotide function enhancer,

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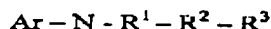
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said DNA molecule comprising a DNA sequence that encodes an antigen, said DNA sequence operatively linked to regulatory sequences which control the expression of said DNA sequence,

said polynucleotide function enhancer is a compound having one of the following formula:



or



or



or



wherein:

Ar is benzene, *p*-aminobenzene, *m*-aminobenzene, *o*-aminobenzene, substituted benzene, substituted *p*-aminobenzene, substituted *m*-aminobenzene, substituted *o*-aminobenzene, wherein the amino group in the aminobenzene compounds can be amino, C<sub>1</sub> - C<sub>5</sub> alkylamine, C<sub>1</sub>-C<sub>5</sub>, C<sub>1</sub>-C<sub>5</sub> dialkylamine and substitutions in substituted compounds are halogen, C<sub>1</sub>-C<sub>5</sub> alkyl and C<sub>1</sub>-C<sub>5</sub> alkoxy;

R<sup>1</sup> is C=O;

R<sup>2</sup> is C<sub>1</sub>-C<sub>10</sub> alkyl including branched alkyls;

R<sup>3</sup> is hydrogen, amine, C<sub>1</sub>-C<sub>5</sub> alkylamine, C<sub>1</sub>-C<sub>5</sub>, C<sub>1</sub>-C<sub>5</sub> dialkylamine;

R<sup>2</sup> + R<sup>3</sup> can form a cyclic alkyl, a C<sub>1</sub>-C<sub>10</sub> alkyl substituted cyclic alkyl, a cyclic aliphatic amine, a C<sub>1</sub>-C<sub>10</sub> alkyl substituted cyclic aliphatic amine, a heterocycle, a C<sub>1</sub>-C<sub>10</sub> alkyl substituted heterocycle including a C<sub>1</sub>-C<sub>10</sub> alkyl N-substituted heterocycle;

R<sup>4</sup> is Ar, R<sup>2</sup> or C<sub>1</sub>-C<sub>5</sub> alkoxy, a cyclic alkyl, a C<sub>1</sub>-C<sub>10</sub> alkyl substituted cyclic alkyl, a cyclic aliphatic amine, a C<sub>1</sub>-C<sub>10</sub> alkyl substituted cyclic aliphatic amine, a heterocycle, a C<sub>1</sub>-C<sub>10</sub>

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proceeds:

151. (previously presented) The method of claim 148 wherein said antigen is an intracellular pathogen antigen.

152. (previously presented) The method of claim 148 wherein said antigen is a viral antigen.

153. (previously presented) The method of claim 152 wherein said viral antigen is of a virus selected from the group consisting of: human immunodeficiency virus, HIV; Human T cell

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leukemia virus, HTLV; influenza virus; hepatitis A virus; hepatitis B virus; hepatitis C virus; human papilloma virus, HPV; Herpes simplex 1 virus, HSV1; Herpes simplex 2 virus, HSV2; Cytomegalovirus, CMV; Epstein-Barr virus, EBR; rhinovirus; and, coronavirus.

**154. (previously presented)** The method of claim 148 wherein said tissue includes skin and muscle.

**155. (previously presented)** The method of claim 154 wherein said tissue is skin.

**156. (previously presented)** The method of claim 154 wherein said tissue is muscle.

**157. (previously presented)** The method of claim 156 wherein said tissue is skeletal muscle.

**158. (previously presented)** The method of claim 149 wherein said DNA molecule is a plasmid.

**159. (previously presented)** The method of claim 149 wherein said antigen is an intracellular pathogen antigen.

**160. (previously presented)** The method of claim 149 wherein said antigen is a viral antigen.

**161. (previously presented)** The method of claim 160 wherein said viral antigen is of a virus selected from the group consisting of: human immunodeficiency virus, HIV; Human T cell leukemia virus, HTLV; influenza virus; hepatitis A virus; hepatitis B virus; hepatitis C virus; human papilloma virus, HPV; Herpes simplex 1 virus, HSV1; Herpes simplex 2 virus, HSV2; Cytomegalovirus, CMV; Epstein-Barr virus, EBR; rhinovirus; and, coronavirus.



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**162. (previously presented)** The method of claim 149 wherein said tissue includes skin and muscle.

**163. (previously presented)** The method of claim 162 wherein said tissue is skin.

**164. (previously presented)** The method of claim 162 wherein said tissue is muscle.

**165. (previously presented)** The method of claim 164 wherein said tissue is skeletal muscle.